

1 IN THE UNITED STATES DISTRICT COURT
2 EASTERN DISTRICT OF MICHIGAN

3
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5 Attorney at Law
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9 Attorney for the Plaintiff

10 Keith Altman
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15 Attorney for the Plaintiff

16 TRUTEK CORP.,
17 Plaintiff,
18 v.
19 BlueWillow Biologics, Inc.
20 ROBIN ROE 1 through 10, gender
21 neutral fictitious names, and ABC
22 CORPORATION 1 through 10
23 (fictitious names).
24 Defendants.

25 CIVIL ACTION No. No. 2:21-cv-10312-SJM-RSW

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28 AMENDED COMPLAINT

1 DEMAND FOR JURY TRIAL

2 PARTIES

3 1. Plaintiff, TRUTEK CORP. ("TRUTEK") is a corporation of the State of New
4 Jersey, with principal offices at 281 East Main Street, Somerville, New
5 Jersey, 08876.
6 2. Upon information and belief, Defendant, BlueWillow Biologics, Inc.
7 ("BLUEWILLOW") is a corporation of the State of Delaware, with a place of
8 business at 2311 Green Road, Suite A, Ann Arbor, Michigan 48105.

FEDERAL SUBJECT MATTER JURISDICTION

3. The subject matter jurisdiction of this Court arises under 28 U.S.C. § 1331 concerning a federal question, the Patent Laws of the United States, 28 U.S.C. §§ 1338(a), (b), and 35 U.S.C. § 271.

IN PERSONAM JURISDICTION

4. The *in personam* jurisdiction of this Court over Defendant BLUEWILLOW is proper under 28 U.S.C. § 1400(b) because the tort of patent infringement occurred in Michigan and BLUEWILLOW has an established place of business in Michigan.

4

VENUE

5. The venue of this Court is proper under the Patent Venue Statute, 28 U.S.C. § 1400(b) since the tort of patent infringement occurred within the State of Michigan, and Defendant BLUEWILLOW has an established place of business thereat, and which is furthermore located within the venue of the Eastern District of Michigan.

11

STATEMENT OF FACTS AND CAUSES OF ACTION

6. Ashok Wahi ("WAHI") is PresidentChief Science an IP Officer of Plaintiff TRUTEK.
7. On November 21, 1995, United States Patent No. 5,468,488 (hereinafter the '488 Patent) was issued to WAHI for his invention titled, "Electrostatically Charged Nasal Application Product and Method." The '488 Patent was assigned to TRUTEK.
8. On October 7, 1997, United States Patent No. 5,674,481 (hereinafter the '481 Patent) was issued to WAHI for his invention titled, "Electrostatically Charged Nasal Topical Application Product." The '481 Patent was assigned to TRUTEK.

1 9. On January 18, 2005, United States Patent No. 6,844,005 (hereinafter the
2 '005 Patent) was issued to WAHI for his invention titled, "Electrostatically
3 Charged Nasal Application Product With Increased Strength." The '005
4 Patent was assigned to TRUTEK.

5 10. On April 24, 2012, United States Patent No. 8,163,802 (hereinafter the '802
6 Patent) was issued to WAHI for his invention titled, "Electrostatically
7 Charged Multi-Acting Nasal Application Product, and Method," on a patent
8 application that was filed at the United States Patent and Trademark Office
9 (USPTO) on May 16, 2009. The '802 Patent was assigned to TRUTEK. The
10 '802 Patent is attached hereto as Exhibit 6.

11 11. The patented technology made it possible for people to apply TRUTEK's
12 manufactured products in and around their nasal passages to reduce reactions
13 to airborne allergens and to reduce or eliminate reactions to viral infections
14 from influenza and the common cold by restricting and inactivating virus
15 sized particles. This is done by establishing an electrostatic charge in and
16 around nasal passages.

17 12. As of the year 1992 going forward, TRUTEK utilized its patented and
18 proprietary trade secret technology to establish proof of concept, develop,
19 formulate, manufacture, sell, and/or license over-the-counter products under
20 the brand name NasalGuard® AllergieBlock®, NasalGuard Cold&Flu Block®,
21 NasalGuard® Multi Acting™, Anti-Stat Enhanced Mask™, NasalGuard
22 Wipes™, NasalGuard Allergie Wipes™, NasalGuard Cold & Flu Wipes™,
23 Skin and Hair super conditioners, Truteks® Skin and Truteks® skin care
24 products, along with electrostatically charged nasal multipurpose products,
25 nasal application (anti-stat) diagnostic products and, associated Technologies
26 and Methodologies, Patents and Pending Patent Applications, also including
27 products under the brand names Chloraseptic Allergen Block and Little
28 Allergies Allergen Block, Eisai Crystal Veil, Eisai Crystal Veil Cool, Nitto

1 Nuru Mask, Nitto NasalGuard, further including but not limited to nasal
 2 application product lines such as gels, pre-moistened products for *e.g.*
 3 applicators, swabs, wipes, etc., sticks, nasal sprays, nasal washes, surgical
 4 masks, and multi-acting/integrated products.

5 13. Claim 1 of the '802 Patent claims a method of applying a formulation to the
 6 skin or tissue of a person's nasal passages in a thin film. The formulation
 7 electrostatically attracts and holds particulate matter to the thin film, and
 8 binds it to the thin film. The bound particulate matter is then inactivated by
 9 at least one ingredient that renders it harmless. One such claimed
 10 inactivating ingredient is benzalkonium chloride (claim 7). This process is
 11 sometimes referred to as "catch, hold, and kill."

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13 BLUEWILLOW'S Nanobio® Protect Products

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14 14. According to information and belief, sometime in 2020, Defendant
 15 BLUEWILLOW manufactured and marketed one or more over-the-counter
 16 pharmaceutical products named NanoBio® Protect ("NANOBIO").
 17 According to information and belief, the NANOBIO products were sold
 18 over-the-counter at least at CVS pharmacies nationwide, and were sold
 19 online to customers by Amazon.com.

20 15. BLUEWILLOW's website advertises—advertised the NANOBIO product
 21 being applied to a customer's nasal passages. Their product forms positively
 22 charged "NanoBio Droplets" that are approximately 600 nanometers¹ in size,
 23 which adhere to nasal membranes. Most harmful particles, such as bacteria
 24 or viruses (referred to as "germs"), are negatively charged. The positively
 25 charged "NanoBio Droplets" attract and bind to these particles. The
 26 NANOBIO product formulation contains benzalkonium chloride (which the
 27 website calls BZK) that adheres to the surface of the "NanoBio droplets."

28 ¹ A nanometer is a billionth of a meter.

1 According to the website, the "NanoBio droplets" surround the germs and
2 "kill them via membrane disruption." (See Exhibit 1 attached hereto.) The
3 NANOBIO product implements the methodology of "catch, hold, and kill."
4 The NANOBIO website "Frequently Asked Questions" section (Exhibit 2)
5 describing the product further enforces this mechanism of action.

6 16. Sometime in 2020, WAHI suspected that the NANOBIO product infringes
7 one or more of TRUTEK's patents. To that end, on June 23, 2020, TRUTEK
8 personnel purchased the NANOBIO product from Amazon.com. After
9 extensive in-house experimentation, it was indicated that the NANOBIO
10 product functions by producing an electrostatic charge in and around the
11 user's nasal passages. It was indicated that NANOBIO product infringes
12 claims of TRUTEK's '802 Patent. On January 14, 2021, TRUTEK personnel
13 purchased a NANOBIO product from CVS, and obtained similar results
14 through in-house experimentation.

15 17. To validate TRUTEK's in-house experimental results, TRUTEK contracted
16 with Alexai Ermakov, Ph.D. to compare the electrostatic charges between
17 BLUEWILLOW's NANOBIO product and TRUTEK's NasalGuard®
18 products. His experiments showed not only that the NANOBIO product
19 exhibited a surface electrostatic charge, but also that the orders of magnitude
20 of the charges of the BLUEWILLOW and TRUTEK products were of the
21 same order of magnitude. Dr. Ermakov's Report is attached hereto as Exhibit
22 3. For further verification, TRUTEK contracted with Electro-Tech Systems
23 ("ETS") in Perkasie, Pennsylvania, to run additional experiments. ETS
24 personnel applied BLUEWILLOW's NANOBIO product and TRUTEK's
25 NasalGuard® product to pig skin swatches. Pig skin is very similar to human
26 skin tissue. The ETS and Ermakov experiments yielded similar results. The
27 NANOBIO product exhibited a surface electrostatic charge of the same order
28 of magnitude as the NasalGuard® product. The ETS report is attached hereto

1 as Exhibit 4.

2 18. On January 31, 2021, Keith Altman, a resident of the State of Michigan,
3 ordered and paid for one unit of NanoBio Protect Nasal Antiseptic online
4 from Amazon.com. The product was to be shipped by Amazon.com to his
5 address in Michigan. Mr. Altman used his computer to place the order, and
6 the computer is located in Michigan, and it was located therein at the time
7 that he placed his order. On February 1, 2021, Mr. Altman received the
8 ordered one unit of NanoBio Protect Nasal Antiseptic in Michigan at the
9 designated Michigan shipping address. A declaration of Keith Altman
10 attesting to these events is attached hereto as Exhibit 5.

11 19. The ability to lessen the reactions to airborne contaminants by creating an
12 electrostatic charge around a person's nasal passages was disclosed in
13 TRUTEK's '488, '481, '005, and '802 Patents. A copy of the '802 Patent is
14 attached hereto as Exhibit 6.

15 20. The ability to lessen the reactions to airborne contaminants by creating an
16 electrostatic charge around a person's nasal passages is inherent in
17 TRUTEK's formulations and manufacturing processes. Efficacy studies
18 show that TRUTEK's methodology presented a viable solution to relief of
19 allergy, cold, and flu symptoms.

20 21. Upon information and belief, just as TRUTEK's products work on allergens
21 and viruses by creating an electrostatic charge around nasal passages and
22 further inactivate said allergens and viruses, the NANOBIO products work
23 the same way.

24 22. At some point after this lawsuit was filed, BLUEWILLOW discontinued
25 sales of the NANOBIO products, and the product descriptions were removed
26 from BLUEWILOW'S website.

27 22.23. The NANOBIO products are sold to customers by Amazon.com as are
28 TRUTEK's competing products also sold thereby. The competitive sales of

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1 the competing NANOBIO products deprive TRUTEK of sales and profits
 2 from its own products.

3 23-24 Upon information and belief, Defendants Robin Roe 1 through 10 and ABC
 4 Corporations 1 through 10 also infringe on the claims of TRUTEK's '802
 5 Patent.

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BLUEWILLOW'S Vaccine Products

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7 25. BLUEWILLOW'S website reference to NANOBIO stated, "[t]he unique
 8 protectiveness of Nanobio® Protect is derived from Bluewillow's patented
 9 nanotechnology. (See Exhibit 1, second page.) No patent numbers were
 10 marked on NANOBIO's packaging.

11 26. According to information and belief, the NANOBIO droplets referred to in
 12 Exhibits 1 and 2 are nanoemulsion nanodroplets.

13 27. A nanoemulsion is an oil-in-water emulsion exitsing in extremely small
 14 nano-droplets that are less than 1,000 nanometers in size.

15 28. According to information and belief, BLUEWILLOW owns all of the
 16 intellectual property assets of Nanobio Corporation.

17 29. The following is a non-exclusive list of United States patents that are
 18 assigned to Nanobio Corporation:

19 a. U.S. Patent No. 8,226,965 B2, issued on July 24, 2012 to James R. Baker,
 20 Jr., et.al., entitled, "Methods of Treating Fungal, Yeast And Mold
 21 Infections."

22 b. U.S. Patent No. 8,703,164 B2, issued on April 22, 2014 to Ted C. Annis,
 23 et.al., entitled, "Compositions For Inactivating Pathogenic
 24 Microorganisms, Methods of Making, the Compositions, and Methods of
 25 Use Thereof.

26 c. U.S. Patent No. 9,131,680 B2, issued on September 15, 2015 to Theodore
 27 C. Annis, et.al., entitled, "Compositions For Inactivating Pathogenic

1 Microorganisms, Methods of Making, the Compositions, and Methods of
 2 Use Thereof.

3 d. U.S. Patent No. 89,144,606 B2, issued on September 29, 2015 to James
 4 R. Baker, Jr., *et.al.*, entitled, "Nanoemulsion Influenza Vaccine."

5 e. U.S. Patent No. 9,492,525 B2, issued on November 15, 2016 to Ali I.
 6 Fattom, *et.al.*, entitled, "Human Respiratory Syncytial Virus Vaccine."

7 f. U.S. Patent No. 9,561,271 B2, issued on February 7, 2017 to Ali I.
 8 Fattom, *et.al.*, entitled, "Nanoemulsion Respiratory Syncytial Virus
 9 (RSV) Subunit Vaccine."

10 g. U.S. Patent No. 10,206,996 B2, issued on February 19, 2019 to Ali I.
 11 Fattom, *et.al.*, entitled, "Herpes Simplex virus Nanoemulsion Vaccine."

12 h. U.S. Patent No. 10,5425,121 B2, issued on January 7, 2020 to Tarek
 13 Hamouda, *et.al.*, entitled, "Nanoemulsion Influenza Vaccine."

14 i. U.S. Patent No. 10,596,251 B2, issued on March 24, 2020 to Ali I.
 15 Fattom, *et.al.*, entitled, "Nanoemulsion Respiratory Syncytial Virus
 16 (RSV) Subunit Vaccine."

17 30. All of the patents listed above disclose and claim vaccines that are
 18 administered nasally and that are contained in or comprise nanoemulsions.

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19 31. The following is a non-exclusive list of United States patents assigned to the
 20 Regents of the University of Michigan (the "Univ. Michigan Patents"), the
 21 inventors of which are current professionals working for BLUEWILLOW:

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22 a. U.S. Patent No. 7,314,624 B2 issued on January 1, 2008 to James R.
 23 Baker, *et.al.*, entitled, "Nanoemulsion Vaccines."

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24 b. U.S. Patent No. 9,974,844 B2 issued on May 22, 2018 to Andrzej Myc, *et.*
 25 *al.*, entitled, "Cancer Vaccine Compositions and Methods of Using the
 26 Same."

27 c. U.S. Patent No. 10,138,279 issued on November 27, 2018 to James R.
 28 Baker, Jr., *et.al.*, entitled, "Compositions and Methods For *Bacillus*"

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1 Antracis Vaccination."

2 32. All of the above listed Univ. Michigan Patents disclose and claim vaccines
 3 that are administered nasally and that are contained in or comprise
 4 nanoemulsions.

5 33. According to information and belief, work performed by current
 6 BLUEWILLOW professionals, which culminated in applications that
 7 ultimately issued as the above Univ. Michigan Patents, was performed while
 8 the inventors were engaged in research at the University of Michigan and
 9 before their involvement at Nanobio Corporation.

10 34. By their very nature, nanoemulsion droplets possess an electrostatic charge.
 11 The polarity of the electrostatic charge of any droplet is the same as for every
 12 other droplet. If this were not so, the droplets would coalesce into a single
 13 liquid, and they would no longer be distinct from each other. The patents
 14 listed above disclose nanoemulsion droplets the electrostatic charges of
 15 which are cationic (*i.e.*, positively charged).

16 35. The nanoemulsion adjuvants disclosed in the patents listed above also
 17 contain biocidic agents. Among the biocidic agents disclosed in the patents
 18 for use in the nanoemulsion adjuvants is benzalkonium chloride.
 19 Benzalkonium chloride is also a cationic agent. Benzalkonium chloride is
 20 also referred to *supra* as "BZK."

21 36. According to information and belief, BLUEWILLOW is currently
 22 developing vaccines, and it has been doing so for a number of years.

23 37. According to information and belief, some or all of the BLUEWILLOW
 24 vaccines that utilize a proprietary technology platform that it calls NanoVax®
 25 NE01 Technology. According to information and belief, NanoVax® NE01
 26 Technology utilizes an oil-in-water nanoemulsion adjuvant to enable
 27 intranasal vaccines for challenging diseases.

28 38. –According to information and belief, BLUEWILLOW'S vaccines are

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1 intended to eombatproduce and immune response in subjects to certain
2 diseases and conditions, and those diseases and conditions include, but are
3 not limited to: (1) anthrax; (2) influenza; (3) COVID-19 and its variants; (4)
4 RSV (Respiratory Syncytial Virus); (4) SARS; (5) sexually transmitted
5 diseases; (6) environmental allergies; (7) food allergies; (8) peanut allergies;
6 and (9) certain forms of cancer.

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7 39. According to information and belief, all of the above listed BLUEWILLOW
8 vaccines utilize nanoemulsions (and are therefore electrostatically charged),
9 contain cationic and biocidic agents, and are intended to be administered to
10 subjects nasally.

11 40. According to information and belief, some or all of the above listed
12 BLUEWILLOW vaccines infringe at least claims 1, 2, 6, and 7 of Trutek's
13 '802 Patent.

14 41. According to information and belief, development of a vaccine against
15 *Bacillus Anthracis* (anthrax) is ongoing being funded in part by a grant from
16 the United States Department of Defense. According to information and
17 belief, this vaccine is currently undergoing phased trials to determine safety
18 and efficacy.

19 42. According to information and belief, development of a vaccine against
20 influenza virus is ongoing being funded in part by a grant from the United
21 States National Institutes of Health (NIH). According to informatin and
22 belief, this vaccine is currently undergoing phased trials to determine safety
23 and efficacy.

24 43. According to information and belief, BLUEWILLOW is collaborating with
25 third parties in its vaccine development effort.

26 44. According to information and belief, BLUEWILLOW has not yet realized
27 revenue from sales of its vaccine products.

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GENERAL ALLEGATIONS

24.45. Plaintiff incorporates all of the above Paragraphs *supra* as though fully restated herein.

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25-46. Plaintiff owns intellectual property related to certain formulations based upon attracting and/or repelling electrostatically charged particles in and around a person's nasal passages by application of a product that maintains an electrostatic charge on the skin or mucous membranes. Plaintiff has expended considerable resources to inventing, formulating, and developing its inventions and products and to protecting its rights therein. Plaintiff holds all rights, title, and interest to its '488, '481, '005, and '802 Patents. The '802 Patent is in full force and effect. TRUTEK is the legal owner of the '802 Patent and possesses all rights of recovery under the patent.

11

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COUNT 4

Infringement of the '802 Patent

26-47. Plaintiff incorporates all of the above Paragraphs *supra* as though fully restated herein.

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48. Plaintiff owns intellectual property relating to an electrostatically charged multi-acting nasal application product and method covered by the '802 patent.

49. Defendants make, use, and intend to sell infringing products, i.e., the BLUEWILLOW vaccines (listed *supra*), which infringe on the '802 Patent, without authority or license from Plaintiff.

50. Defendants infringe at least claims 1, 2, 6, and 7 of the '802 Patent because the BLUEWILLOW vaccines possess an electrostatic charge when applied to a person's nasal passages, and they contain a cationic agent and a biocidic agent.

1 51. Plaintiff has been damaged as a result of Defendants' infringement of the '802
 2 Patent, and will continue to be damaged unless such infringement is enjoined
 3 by this Court pursuant to 35 U.S.C. § 283.

4 52. Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to damages adequate to
 5 compensate in an amount not less than a fair and reasonable royalty.

6 53. Alternatively, Plaintiff is entitled to a judgment from the Court, which
 7 enjoins sales or commercialization by BLUEWILLOW of its vaccines until
 8 after expiration of the '802 Patent.

9 //

10 COUNT 2

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11 Infringement of the '802 Patent

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12 54. Plaintiff incorporates all of the above Paragraphs *supra* as though fully
 13 restated herein.

14 27.55 Plaintiff owns intellectual property relating to an electrostatically charged
 15 multi-acting nasal application product and method covered by the '802
 16 patent.

17 28.56 Defendants distributed, made, used, offered to sell and/or sold
 18 infringing products, i.e., the NANOBIO products.

19 29.57 Defendants distributed, made, used, offered to sell and/or sold
 20 infringing products, i.e., the NANOBIO products, which infringe on the '802
 21 Patent, without authority or license from Plaintiff.

22 30.58 Defendants infringe at least claims 1, 2, 6 and 7 of the '802 Patent because
 23 the NANOBIO products possess an electrostatic charge when applied to a
 24 person's nasal passages, and they use benzalkonium chloride as a cationic
agent and also as a biocide/biocidic agent.

26 31.59 Plaintiff has been damaged as a result of Defendants' infringement of the '802
 27 Patent, and will continue to be damaged unless such infringement is enjoined
 28 by this Court pursuant to 35 U.S.C. § 283.

1 32.60 Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to damages adequate to
2 compensate in an amount not less than a fair and reasonable royalty.

3 61. Alternatively, as the NANOBIO products are no longer being sold by
4 Defendant, Plaintiff is entitled to damages adequate to compensate in an
5 amount not less than the profits realized by Defendant for past sales of the
6 NANOBIO products.

7 62. Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to damages adequate to
8 compensate in an amount not less than a fair and reasonable royalty.

9 63. Plaintiff is entitled to a judgment from the Court, which enjoins sales or
10 commercialization by BLUEWILLOW of its NANOBIO products until after
11 expiration of the '802 Patent.

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PRAYER FOR RELIEF

14 Wherefore, Plaintiff prays that:

15 1. Defendants be required to pay over and account to Plaintiff for all gains,
16 profits, and advantages derived from the infringement of its '802 Patent
17 beginning April 24, 2012, based upon manufacture, sales, and/or use of the
18 NANOBIO products in the United States and anywhere in the world, or by
19 way of international commerce with the United States.

20 2. Defendants be enjoined from manufacturing and/or selling the NANOBIO
21 products in the United States, either directly or indirectly.

22 3. Defendants be enjoined from actively inducing others to sell the NANOBIO
23 products in the United States, either directly or indirectly.

24 4. Defendants be enjoined from exporting the NANOBIO products from the
25 United States, either directly or indirectly.

26 5. Defendants be enjoined from manufacturing and/or selling the
27 BLUEWILLOW vaccines until after expiration of the '802 Patent.

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28 6. Defendants be enjoined from actively inducing others to sell the

BLUEWILLOW vaccines until after expiration of the '802 Patent.

7. Defendants be enjoined from exporting the BLUEWILLOW vaccines until after expiration of the '802 Patent.

5.8. Plaintiff prays for such other and further relief as the Court may deem to be just and proper.

11

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DEMAND FOR DISCOVERY OF INSURANCE COVERAGE

Pursuant to Defendants' discovery obligations, demand is made that all Defendants disclose to the Plaintiff whether or not there are any insurance agreements or policies under which any person or firm carrying on an insurance business may be liable to satisfy part or all of a judgment which may be entered in this action or indemnify or reimburse for payments made to satisfy the judgment and provide Plaintiff with true copies of those insurance agreements or policies, including, but not limited to, any and all declarations sheets. This demand shall include and cover not only primary coverage, but also any and all excess, catastrophe and umbrella policies.

11

DEMAND FOR A JURY TRIAL

Plaintiff hereby demands a trial by jury of all issues triable of right by a jury.

Dated: February 9, 2021April, 2022

s/ Stanley H. Kremem

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